

SAS-dsh 08/15/06 4239-67021-06 506065 E-184-2002/0-US-03



INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Attorney Docket Number	4239-67021-06
Application Number	10/533,634
Filing Date	April 29, 2005
First Named Inventor	Klinman
Art Unit	1648
Examiner Name	Emily M. Le

U.S. PATENT DOCUMENTS

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Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		6,194,388	2/27/2001	Krieg, et al.
		6,207,646	3/27/2001	Krieg, et al.
		6,214,806	4/10/2001	Krieg, et al.
		6,218,371	4/17/2001	Krieg, et al.
		6,239,116	5/29/2001	Krieg, et al.
		6,339,068	1/15/2002	Krieg, et al.
		6,406,705	6/18/2002	Davis, et al.
		6,423,539	7/23/2002	Fong, et al.
		6,428,788	8/6/2002	Debinski, et al.
		6,429,199	8/6/2002	Krieg, et al.
		6,498,148	12/24/2002	Raz
		6,514,948	2/4/2003	Raz, et al.
		6,534,062	3/18/2003	Krieg, et al.
		6,552,006	4/22/2003	Raz, et al.
		6,562,798	5/13/2003	Schwartz
		6,589,940	7/8/2003	Raz, et al.

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Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		6,610,661	8/26/2003	Carson, et al.
		6,613,751	9/2/2003	Raz, et al.
		6,653,292	11/25/2003	Krieg, et al.
		2001-0034330	10/25/2001	Kensil
		2001-0036462	11/1/2001	Fong, et al.
		2001-0044416	11/22/2001	McCluskie, et al.
		2001-0046967	11/29/2001	Van Nest
		2002-0006403	1/17/2002	Yu, et al.
		2002-0028784	3/7/2002	Van Nest
		2002-0042383	4/11/2002	Yew, et al.
		2002-0042387	4/11/2002	Raz, et al.
		2002-0055477	5/9/2002	Van Nest, et al.
		2002-0064515	5/30/2002	Krieg, et al.
		2002-0065236	5/30/2002	Yew, et al.
		2002-0086295	7/4/2002	Raz, et al.
		2002-0086839	7/4/2002	Raz, et al.

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Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		2002-0090724	7/11/2002	Taylor, et al.
		2002-0091095	7/11/2002	Phillips, et al.
		2002-0091097	7/11/2002	Bratzler, et al.

FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		EPO	EP 1 198 249	4/24/2002	
		WIPO	WO 92/18522	10/29/1992	
		WIPO	WO 94/19945	9/15/1994	
		WIPO	WO 97/28259	8/7/1997	
		WIPO	WO 99/11275	3/11/1999	
		WIPO	WO 00/06588	2/0/2000	
		WIPO	WO 00/20039	4/13/2000	
		WIPO	WO 00/21556	4/20/2000	
		WIPO	WO 00/61151	10/19/2000	

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		WIPO	WO 00/62787	10/26/2000	
		WIPO	WO 00/67023	11/9/2000	
		WIPO	WO 01/00232	1/4/2001	
		WIPO	WO 01/02007	1/11/2001	
		WIPO	WO 01/12223	2/22/2001	
		WIPO	WO 01/22990	4/5/2001	
		WIPO	WO 01/51500	7/19/2001	
		WIPO	WO 01/55341	8/2/2001	
		WIPO	WO 01/68077	9/20/2001	
		WIPO	WO 01/68103	9/20/2001	
		WIPO	WO 01/68116	9/20/2001	
		WIPO	WO 01/68117	9/20/2001	

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		ANFOSSI, et al., "An oligomer complementary to c-myc-encoded mRNA inhibits proliferation of human myeloid leukemia cell lines". Proc. Natl. Acad. Sci. USA 86:3379-3383 (1989).
		BAUER, et al., "Bacterial CpG-DNA Triggers Activation and Maturation of Human CD11c-, CD123+ Dendritic Cells". J. Immunol. 166:5000-5007 (2001).
		BENIMETSKAYA, et al., "Formation of a G-tetrad and higher order structures correlates with biological activity of the RelA (NF-kBp65) 'antisense' oligodeoxynucleotide". Nucleic Acids Research 25(13):2648-2656 (1997).
		BOGGS, et al., "Characterization and modulation of immune stimulation by modified oligonucleotides". Antisense Nucl. Acid Drug Dev. 7(5):461-471 (1997).
		BRANDA, et al., "Amplification of antibody production by phosphorothioate oligodeoxynucleotides". J. Lab Clin. Med. 128(3):329-338 (1996).
		CHU, et al., "CpG oligodeoxynucleotides act as adjuvants that switch on T helper 1 (Th1) immunity". J. Exp. Med. 186(10):1623-1631 (1997).
		DEML, et al., "Immunostimulatory CpG motifs trigger a T Helper-1 immune response to Human Immunodeficiency Virus Type-1 (HIV-1) gp160 envelope protein". Clin. Chem. Lab. Med. 37(3):199-204 (1999).
		GAO, et al., "Phosphorothioate oligonucleotides are inhibitors of human DNA polymerases and Rnase H: Implications for antisense technology". Mol. Pharmacol. 41:223-229 (1992).
		GURSEL, et al., "Differential and Competitive Activation of Human Immune Cells by Distinct Classes of CpG Oligodeoxynucleotide". J. Leuko. Biol. 71:813-820 (2002).
		HALPERN, et al., "Bacterial DNA induces murine interferon-gamma production by stimulation of interleukin-12 and tumor necrosis factor-alpha". Cell Immunol. 167(1):72-78 (1996).
		ISHIBASHI, et al., "Sp1 Decoy Transfected to Carcinoma Cells Suppresses the Expression of Vascular Endothelial Growth Factor, Transforming Growth Factor β , and Tissue Factor and Also Cell Growth and Invasion Activities". Cancer Research 60:6531-6536 (2000).
		IVERSEN, et al., "Pharmacokinetics of an antisense phosphorothioate oligodeoxynucleotide against rev from human immunodeficiency virus type 1 in the adult male rat following single injections and continuous infusion". Antisense Res. Dev. 4:43-52 (1994).
		JILEK, et al., "Antigen-Independent Suppression of the Allergic Immune Response to Bee Venom Phospholipase A2 by DNA Vaccination in CBA/J Mice". J. Immunol. 166:3612-3621 (2001).
		KADOWAKI, et al., "Distinct CpG DNA and Polyinosinic-Polycytidylic Acid Double Stranded RNA, Respectively, Stimulate CD11c- Type 2 Dendritic Cell Precursors and CD11c+ Dendritic cells to Produce Type I IFN". J. Immunol. 166:2291-2295 (2001).
		KLINMAN, et al., "Activation of the innate immune system by CpG oligodeoxynucleotides: immunoprotective activity and safety". Springer Semin. Immunopathol. 22:173-183 (2000).
		KRIEG, et al., "CpG motifs in bacterial DNA and their immune effect". Annu. Rev. Immunol. 20:709-760 (2002).

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	KRIEG, et al., "Brief Communication: Oligodeoxynucleotide Modifications Determine the Magnitude of B-Cell Stimulation by CpG Motifs". <i>Antisense & Nucleic Acid Drug Development</i> 6:133-139 (1996).
	KRIEG, et al., "Leukocyte stimulation by oligodeoxynucleotides". <i>Applied Antisense Oligonucleotide Tech. (BOOK):431-448</i> (1998).
	KRIEG, et al., "CpG DNA: A pathogenic factor in systemic lupus erythematosus?". <i>J. Clin. Immunol.</i> 15(6):284-292 (1995).
	KRIEG, et al., "A role for endogenous retroviral sequences in the regulation of lymphocyte activation". <i>J. Immunol.</i> 143(8):2448-2451 (1989).
	KRIEG, et al., "CpG motifs in bacterial DNA trigger direct B-cell activation". <i>Nature</i> 374:546-549 (1995).
	KRUG, et al., "Identification of CpG Oligonucleotide Sequences with High Induction of IFN- α / β in Plasmacytoid Dendritic Cells". <i>Eur. J. Immunol.</i> 31:2154-2163 (2001).
	KRUG, et al., "Toll-like Receptor Expression Reveals CpG DNA as a Unique Microbial Stimulus for Plasmacytoid Dendritic Cells Which Synergizes With CD40 Ligand to Induce High Amounts of IL-12". <i>Eur. J. Immunol.</i> 31:3026-3037 (2001).
	KURAMOTO, et al., "Oligonucleotide sequences required for natural killer cell activation". <i>Jpn. J. Cancer Res.</i> 83:1128-1131 (1992).
	LANG, et al., "Guanosine-rich oligodeoxynucleotides induce proliferation of macrophage progenitors in cultures of murine bone marrow cells". <i>Eur. J. Immunol.</i> 29:3496-3506 (1999).
	LAPATSCHEK, et al., "Activation of Macrophages and B Lymphocytes by an Oligodeoxynucleotide Derived from an Acutely Pathogenic Simian Immunodeficiency Virus". <i>Antisense Nucleic Acid Drug Dev.</i> 8(5):357-370 (1998).
	MALTESE, et al., "Sequence context of antisense RelA/NF- κ B phosphorothioates determines specificity". <i>Nucleic Acids Research</i> 23(7):1146-1151 (1995).
	MANZEL, et al., "Lack of Immune Stimulation by Immobilized CpG-oligonucleotide". <i>Antisense & Nucleic Acid Drug Development</i> 9(5):459-464 (1999).
	MATSON, et al., "Nonspecific suppression of [3H]thymidine incorporation by control oligonucleotides". <i>Antisense Res. Dev.</i> 2(4):325-330 (1992).
	MCINTYRE, et al., "A sense phosphorothioate oligonucleotide directed to the initiation codon of transcription factor NF- κ B p65 causes sequence-specific immune stimulation". <i>Antisense Res. Dev.</i> 3(4):309-322 (1993).
	PISETSKY, "Immunological consequences of nucleic acid therapy". <i>Antisense Res. Dev.</i> 5:219-225 (1995).
	PRASAD, et al., "Oligonucleotides Tethered to a Short Polyguanylic Acid Stretch are Targeted to Macrophages: Enhanced Antiviral Activity of a Vesicular Stomatitis Virus-Specific Antisense Oligonucleotide". <i>Antimicrobial Agents and Chemotherapy</i> 43(11):2689-2696 (Nov. 1999).
	RAZ, et al., "Intradermal gene immunization: the possible role of DNA uptake in the induction of cellular immunity to viruses". <i>Proc. Natl. Acad. Sci. USA</i> 91:9519-9523 (1994).
	ROMAN, et al., "Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants". <i>Nature Med.</i> 3(8):849-854 (1997).

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	SCHWARTZ, et al., "CpG motifs in bacterial DNA cause inflammation in the lower respiratory tract". J. Clin. Invest. 100(1):68-73 (1997).
	STACEY, et al., "Immunostimulatory DNA as an adjuvant in vaccination against Leishmania major". Infect. Immun. 67:3719-3726 (1999).
	TOKUNAGA, et al., "A synthetic single-stranded DNA, poly(dG, dC), induces interferon- α/β and γ , augments natural killer activity and suppresses tumor growth". Jpn. J. Cancer Res. 79:682-686 (1998).
	TOKUNAGA, et al., "Synthetic oligonucleotides with particular base sequences from the cDNA encoding proteins of Mycobacterium bovis BCG induce interferons and activate natural killer cells". Microbiol. Immunol. 36(1):55-66 (1992).
	VERTHELYI, et al., "Human Peripheral Blood Cells Differentially Recognize and Respond to Two Distinct CpG Motifs". J. Immunol. 166:2372-2377 (2001).
	VERTHELYI, et al., "CpG Oligodeoxynucleotides as Vaccine Adjuvants in Primates". J. Immunol. 168:1659-1663 (2002).
	WEINER, et al., "Immunostimulatory oligodeoxynucleotides containing the CpG motif are effective as immune adjuvants in tumor antigen immunization". Proc. Natl. Acad. Sci. USA 94:10833-10837 (1997).
	YAMAMOTO, et al., "Ability of oligonucleotides with certain palindromes to induce interferon production and augment natural killer cell activity is associated with their base length". Antisense Res. Dev. 4:119-123 (1994).
	YAMAMOTO, "Unique palindromic sequences in synthetic oligonucleotides are required to induce inf and augment INF-mediated natural killer activity". J. Immunol. 148(12):4072-4076 (1992).
	YAMAMOTO, et al., "Synthetic oligonucleotides with certain palindromes stimulate interferon production of human peripheral blood lymphocytes in vitro". Jpn. J. Cancer Res. 85:775-779 (1994).
	YAMAMOTO, et al., "Mode of action of oligonucleotide fraction extracted from Mycobacterium bovis BeG". Kekkaku 69(9):29-32 (1994).
	YAMAMOTO, et al., "Lipofection of synthetic oligodeoxyribonucleotide having a palindromic sequence AACGTT to murine splenocytes enhances interferon production and natural killer activity". Microbiol. Immunol. 38(10):831-836 (1994).
	YASWEN, et al., "Effects of Sequence of Thioated Oligonucleotides on Cultured Human Mammary Epithelial Cells". Antisense Research and Development 3:67-77 (1993).
	YI, et al., "IFN- γ promotes IL-6 and IgM secretion in response to CpG motifs in bacterial DNA and oligonucleotides". J. Immunol. 156:558-564 (1996).
	ZELPHATI, et al., "Inhibition of HIV-1 Replication in Cultured Cells with Antisense Oligonucleotides Encapsulated in Immunoliposomes". Antisense Res. Dev. 3:323 (1993).
	Decision of Interference No. 105,171, The Regents of California versus University of Iowa, Coley Pharmaceutical Group, Inc. and The United States of America. July 17, 2006.

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